REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

I. Status of the Claims

Claims 4-5, 9-15, 17, 53-54, 58-63 and 73 are cancelled without prejudice or disclaimer thereof. Applicants reserve the right to pursue the subject matter of any cancelled claims. Claims 1 and 50 have been amended with exemplary support in the original specification, *e.g.*, in paragraph [0033] bridging pages 11 and 12; at page 12, paragraph [0035]; and in paragraph [0111] bridging pages 34 and 35. Claims 2-3, 6-8, 16, 18-25, 52, 55-57, 64, 68 and 72 have been amended for greater clarity. New claims 74-100 have been added with exemplary support in the original claims.

Because no new matter is introduced, Applicants respectfully request entry of the amendments. Upon entry, Claims 1-3, 6-8, 16, 18-52, 55-57, 64-72 and 74-100 are pending, with claims 26-49 withdrawn from examination.

II. Rejection of Claims under 35 U.S.C. §103(a)

A. Stuengmann and Bosch

Claims 1-17 and 50-67 are rejected under 35 U.S.C. §103(a) for alleged obviousness over PCT Publication No. WO 99/09988 by Struengmann et al. ("Struengmann") in view of U.S. Patent No. 5,510,118 to Bosch et al. ("Bosch"). Claims 4-5, 9-15, 17, 53-54, 58-63 are cancelled thereby rendering the rejection moot. Applicants respectfully traverse the rejection of the remaining claims.

(i) The Examiner bears the initial burden of establishing a prima facie case of obviousness.

Struengmann relates to a pharmaceutical composition comprising meloxicam prepared by homogenization in the presence of surfactants, co-solvents, hydrotropic agents, alkalizing agents or cyclodextrins, *etc*. Struengmann fails to meet at least the claim limitations of a meloxicam particle size of less than 2000 nm and a surface stabilizer adsorbed on the surface of the meloxicam particles.

The Examiner acknowledges that Struengmann does not teach the active agent particle size but improperly states that "absent of evidence to the contrary, the burden is shifted to applicant to show that the obtained meloxicam powder of Struengmann does not have the claimed average particle size" (Office Action, page 4, lines 5-7).

MPEP 2142 clearly states that the Examiner bears the initial burden of establishing the *prima facie* case of obviousness: "The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness."

Accordingly, the Examiner is required to articulate that the cited references meet all claim limitations to sufficiently support the rejection rationale.

(ii) The Examiner's reliance on "inherence" is improper and repetitive.

By the same token, the Examiner inappropriately relied on "inherency" in her assertion that "the burden is shifted to applicant to show that the meloxicam composition of Struengmann does not necessarily produce the T_{max} or C_{max} value being claimed" because these values are deemed to be inherent properties of the claimed composition. Office Action, page 5, first full paragraph.

Applicants respectfully urge that the Examiner take full consideration of all arguments submitted in prior responses and made of record. As submitted in the response dated June 29, 2009, MPEP 2112.01 (II) sets forth the prerequisite for invoking "inherency". This MPEP section notes that it is the Examiner's burden to prove that the claimed composition is identical to the prior-art product, such that the claimed properties **necessarily** flow from the prior-art teachings. *See* pages 33-34. Because the Examiner has not yet proved that Struengmann's composition meets all limitations of the claimed composition, *e.g.*, the meloxicam particle size and a surface stabilizer adsorbed on the surface of the meloxicam particles, it is not evident that Struengmann would have the same pharmacokinetic profiles of the claimed composition. The prior arguments concerning inherency are not repeated in this response and are incorporated by reference.

(iii) The combined teachings of the cited references fail to render the claimed invention obvious.

The claimed invention, as prescribed by claims 1, 74 and 87, is directed to pharmaceutical dosage forms suitable for intravenous injection. The dosage forms comprise meloxicam particles having an effective average particle size of less than 2000 nm and at least one surface stabilizer adsorbed on the surface of the meloxicam particles.

To arrive at the claimed invention, one skilled in the art would have had to chose an intravenous dosage form, the active agent – meloxicam, and the specific surface stabilizer as recited in claim 1. In the absence of the benefit of having the claimed invention as a roadmap, one skilled in the art would not have any reason to select this specific combination to obtain the claimed invention. Therefore, the claimed invention is non-obvious over the cited references.

B. Struengmann, Desai or Courteille

Claims 18-25 and 68-72 are rejected under 35 U.S.C. §103(a) for alleged obviousness over Struengmann in view of PCT Publication No. WO 01/45706 by Desai et al. ("Desai") or

U.S. Patent No. 5,384,124 to Courteille et al. ("Courteille"). Claims 4-5, 9-15, 17, 53-54, 58-63 are cancelled thereby rendering the rejection moot. Applicants respectfully traverse the rejection of the remaining claims.

Desai and Courteille are cited for the alleged teaching of a second particle population but fail to compensate for the deficiencies of Struengmann as stated above. Moreover, the claims at issue are non-obvious for depending either directly or indirectly from a non-obvious base claim. Withdrawal of the rejection is respectfully requested.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Feb 3, 2010 By _____

FOLEY & LARDNER LLP
Customer Number: 31049
Telephone: (202) 672-5538
Facsimile: (202) 672-5399

Michele M. Simkin
Attorney for Applicant
Registration No. 34,717